

Dear Federal Trade Commissioners:

I write regarding the recent FTC hearing on advertising for over-the-counter (OTC) homeopathic products and wish to share data on several aspects to inform the ongoing discussion.

- 1) Homeopathic products are remarkably safe with low rates of adverse effects.
  - a) In 2000 Dantas and Rampes published a systematic review of the literature from 1970-1995 (1). They found 19 clinical trials with detailed information on adverse events and found a mean incidence of adverse events of 9.4 in the homeopathic groups and 6.17 in the placebo groups. The adverse events were mild and transient. The majority of case reports described aggravations of pre-existing symptoms rather than new symptoms and the overall level of causal association was low. Some reports described products that were mislabeled as homeopathic. For homeopathic pathogenetic trials, there was great heterogeneity. The mean incidence of effects was 54%, and overall they were similar to placebo effects in phase I RCTs.
  - b) The health technology assessment commissioned by the Swiss government examined the safety of homeopathy and concluded that “the use of medium and high potencies is free from toxic and unexpected organ effects” (2).
  - c) In 2012, a highly publicized paper on this topic was published by Posadzki and colleagues (3). The senior author, Professor Ernst, is a well-known critic of homeopathy. In this systematic review of the literature from 1978 – 2010 the authors found a total of 1159 case reports of adverse events from homeopathy published from 17 different countries. The adverse events ranged from mild to severe and included 4 fatalities. The most common adverse events were allergic reactions and intoxications. Upon examining the paper in further detail, one finds that 1070 of the reports are of “unspecified remedies” reported to a German poison control center, much like the reports from our own National Poison Data System. There is no validation that all of those 1070 reports are of actual homeopathic products and the vast majority of these cases represent accidental ingestions by young children with limited or no side effects. On reviewing the remaining 89 cases, many are again of unspecified compounds. In other words, we don’t know if they are really homeopathic medicines, and if they are, whether they are single or complex products, or have other non-homeopathic ingredients added to them. Some of the compounds ingested are reported by name and are clearly not traditional homeopathic medicines, and may contain non-homeopathic ingredients (4). Nearly all of the reports lack documentation of concomitant conventional medical treatments. Several did use traditional homeopathic medicines but in very low dilutions (mother tinctures, or 1X potency, that is  $10^{-1}$ ) which would generally not be prescribed by a homeopathic providers or available OTC. Finally, several of the adverse events are clearly misattributed (5). For example, Posadzki and colleagues attributed a case of bladder cancer that developed 7 years following homeopathic treatment to the homeopathic medicine that was received. In summary, it is rather remarkable that a review of 32 years’ worth of literature across 17 countries, many in which homeopathy is used quite widely by the general population, found little evidence for serious toxicity from homeopathic treatment.
- 2) Consumers predominantly use homeopathic products to treat self-limited conditions and perceive it to be helpful in maintaining health and well-being. In collaboration with my colleagues at Harvard Medical School, I have been analyzing data from the 2012 National Health Interview Survey on use of homeopathic medicines among U.S. adults. The manuscript detailing our findings is currently under review. To summarize our findings pertinent to the FTC’s interests, the majority of adults who use homeopathic products use them for self-limited conditions such as colds and

musculoskeletal pain. Those who use homeopathic products are more likely to rate them as helpful for a health-related condition than individuals who use herbs and dietary supplements.

- 3) As a clinician who regularly sees patients who are using a variety of different forms of complementary and conventional health approaches, those I see who use OTC homeopathic products are generally well-informed and often find them beneficial.
- 4) It is important to distinguish products that are truly homeopathic and conform to the FDA and HPCUS guidelines vs. those which claim to be homeopathic on their label but contain non-homeopathic ingredients and misrepresent their products. The FDA has rightly cracked down on a number of these products in recent years. These products which misrepresent themselves as “homeopathic” are the major contributor to ongoing concerns about safety and lack of clinical experience as they have not been validated through the traditional proving process as outlined in the HPCUS.
- 5) A substantial body of evidence suggests that the effects ascribed to homeopathy are more than placebo effects. This evidence includes meta-analyses and reviews of clinical trials (2,6,7), high quality individual RCTs (8–12), observational studies (13), animal models (14), and *in vitro* studies (15), to name a few. In evaluating this literature, it is important to carefully analyze the quality of the studies and methodology used as several highly publicized reports claiming no effect of homeopathy beyond placebo have had significant methodological flaws that affect the resulting data and its interpretation (16,17, 18). Certainly more data, and more repetitions of positive studies are needed. This is particularly challenging given the current funding and grant review environment. Nonetheless, there are a number of non-homeopathic OTC products currently on the market for which there is little or no data of efficacy.

Thank you for your consideration. If I can be of further service in interpreting this literature or answering questions, please do not hesitate to contact me.

Sincerely,

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#### Citations:

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